K093072

DentalEZ, Inc. StarDental Division	Section 5
510(k) Premarket Notification StarCare Handpiece Maintenance Unit	510(k) Summary

Section 5: 510(k) Summary

Company:

DentalEZ Inc., StarDental Division
Owner/operator number 2520265

DEC 2 8 2009

Contact Person:

Dale Braas, Engineering/Quality Manager
Kay Engle, Regulatory Affairs Supervisor
DentalEZ Inc., StarDental Division
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161
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Proprietary/Trade Name:

StarCare Handpiece Maintenance Unit

Classification:

Handpiece, Air-powered, Dental (21 C.F.R. § 872.4200, Product code EFB)

Predicate Device:

Statmatic, manufactured by SciCan LTD. Ontario, Canada (K073319)
Lubrina, manufactured by J. Morita USA, Inc., Irvine, CA. (K070074)
Assistina, manufactured by A-Dec Incorporated, Newburg, OR (K010127)

StarCare Handpiece Maintenance Unit has similar intended uses, similar methods of operation and similar technology to the previously cleared predicate devices. Although minor differences exist between the StarCare Handpiece Maintenance Unit and predicate devices, they do not present any new questions of safety or effectiveness.

Device Description:

The StarCare Handpiece Maintenance Unit is used for the cleaning, i.e. purging of old lubricant, and lubrication of lubricated high speed handpieces, electric micromotor attachments and handpiece turbines. The unit consists of two connections for high speed handpieces, one connection for electric micromotor

attachments and one connection for handpiece turbine cleaning. The unit supplies cleaner and lubricant to the connection only when a high speed handpiece or electric micromotor attachment is present. The handpiece turbine cleaning function is independent of the high speed handpiece and electric micromotor attachment cleaning and lubrication function.

Two reservoirs within the unit supply the cleaner and lubricant to the individual stations. These reservoirs are clearly marked regarding the contents of the reservoir. The cleaner and lubricant are delivered to the high speed handpiece and electric micromotor attachment connection via tubes controlled by the activation of magnetic valves. The liquid is dispensed by pressurized air to the high speed handpiece and electric micromotor attachment.

Intended Use:

The StarCare Handpiece Maintenance Unit is intended for the internal cleaning, i.e. purging of old lubricant, and the lubrication of air-driven high speed handpieces, electric micromotor attachments and turbines used in dentistry.

StarCare Handpiece Maintenance Unit should be used only after the handpieces have been externally cleaned and prior to sterilization.

Technological Characteristics:

The StarCare Handpiece Maintenance Unit is a self-contained cleaning and lubrication system that can clean and lubricate up to two high speed handpieces and one electric micromotor attachment at the same time. Indicator lights on the front panel of the unit, show which handpiece station is currently being serviced. The cleaner and lubricant are pumped from separate reservoirs located within the unit. The unit detects if a high speed handpiece or electric micormotor attachment is connected and delivers cleaner and lubricant only to the occupied stations. After cleaning and lubrication cycle a burst of compressed air is forced into the high speed handpiece or electric micromotor attachment to purge the instrument of excess cleaner, lubricant and debris.

The handpiece turbine cleaning function of the StarCare Handpiece Maintenance Unit is independent of the high speed handpiece and electric micromotor attachment cleaning and lubrication. With the front door of the unit open, the operator holds the handpiece in place during the handpiece turbine cleaning process. After the cleaning and lubrication cycle a burst of compressed air is forced into the chuck to purge the excess cleaner, lubricant and debris. An indicator light on the front panel illuminates during the cleaning process.

The following table summarizes the comparison of the StarCare Handpiece Maintenance Unit to the predicate devices for various technological characteristics.

Technological Characteristics	Predicate Device Comparison conclusion
Indication for use	Similar
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical Safety	Similar

Substantial Equivalence:

The determination of substantial equivalence is based on the premise that the proposed device and the predicate devices have the same intended use, similar technology and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Kay Engle
Regulatory Affairs Supervisor
DentalEZ Incorporated
StarDental Division
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

JAN 21 2010

Re: K093072
Trade/Device Name: StarCare Handpiece Maintenance Unit
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 29, 2009
Received: September 30, 2009

Dear Ms. Engle:

This letter corrects our substantially equivalent letter of December 28, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: StarCare Handpiece Maintenance Unit

Indications for Use:

The StarCare Handpiece Maintenance Unit is intended for the internal cleaning, i.e purging of old lubricant, and the lubrication of air-driven high speed handpieces, electric micromotor attachments and turbines used in dentistry.

StarCare Handpiece Maintenance Unit should be used only after the handpieces have been externally cleaned and prior to sterilization.

CAUTION: Federal law restricts this device to sale by or on the order of a dentist.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R.S. Beth DDS for Dr. K.P. Mulay (Acting)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093072